IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9084

Bartle, J. June 5, 2013

Susan E. Whiteoak ("Ms. Whiteoak" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Robert Whiteoak, Ms. Whiteoak's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael N. Rubinstein, M.D., F.A.C.C. Dr. Rubinstein is no stranger to this litigation. According to the Trust, Dr. Rubinstein has signed at least 213 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated April 27, 2002, Dr. Rubinstein attested in Part II of claimant's Green Form that Ms. Whiteoak suffered from severe mitral regurgitation and

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3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

pulmonary hypertension.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $486,424.[5]

In the report of claimant's echocardiogram, Dr. Rubinstein stated that "[m]ild pulmonary hypertension is evident with the pulmonary artery systolic pressure calculated to be 46 mmHg." Pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic artery pressure > 40 mm Hg measured by cardiac catheterization or > 45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id. § IV.B.2.c.(2)(b)iv).

In July, 2005, the Trust forwarded the claim for review by David I. Silverman, M.D., one of its auditing cardiologists. In audit, Dr. Silverman determined that there was no reasonable medical basis for Dr. Rubinstein's representation that Ms. Whiteoak had pulmonary hypertension secondary to moderate or

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4. In addition, Dr. Rubinstein attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Pulmonary hypertension is one of the complicating factors needed to qualify for a Level II claim. See id. § IV.B.2.c.(2)(b)iv). Although the Trust disputes claimant's level of mitral regurgitation as well, we need not resolve this issue given our determination as to Ms. Whiteoak's pulmonary hypertension.

greater mitral regurgitation. Dr. Silverman stated that, "[s]ince moderate [mitral regurgitation] is not verified, pulmonary hypertension referable to [mitral regurgitation] cannot be claimed."[6]

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, Ms. Whiteoak argued that there is a reasonable medical basis for Dr. Rubinstein's representation that claimant had pulmonary hypertension. To that end, claimant submitted videotaped statements under oath of Dr. Rubinstein, Mark M. Applefeld, M.D., F.A.C.C., and Duncan Salmon, M.D., wherein each cardiologist explained how he concluded that claimant had pulmonary hypertension. Claimant also submitted curricula vitae

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6. At audit, Dr. Silverman determined that there was no reasonable medical basis for Dr. Rubinstein's representation that Ms. Whiteoak had severe mitral regurgitation because the echocardiogram demonstrated only mild mitral regurgitation of 11%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

for these physicians. In addition, claimant submitted Part II of Green Forms completed by Dr. Rubinstein, Dr. Applefeld, and Dr. Salmon, which were based on claimant's April 27, 2002 echocardiogram. Each cardiologist concluded that claimant had pulmonary hypertension.

Claimant also argues that the auditing cardiologist should not simply substitute his opinion for that of the attesting physician and that inter-reader variability may account for the difference of opinion among cardiologists. In addition, claimant contends that three cardiologists reviewed her echocardiograms and found that she had pulmonary hypertension and, therefore, there is a reasonable medical basis for her claim.[8]

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On January 12, 2006, we

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8. Claimant also argues that, in reviewing her claim, the court should consider that certain claims have passed audit "mistakenly" and that certain auditors have been removed for undisclosed conflicts. We disagree. Claimant does not attempt to explain how these circumstances had any impact on Dr. Silverman's review of her specific claim. As we consistently have stated, the relevant inquiry is whether a claimant has established a reasonable medical basis for his or her claim, an inquiry that is to be made on a claim-by-claim basis. See, e.g., PTO No. 6280 at 9 (May 19, 2006).

issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant served a response upon the Special Master. The response, however, contained a Declaration of Frank R. Miele regarding the issue of degradation resulting from copying videotapes. The Special Master denied claimant's request to submit this new evidence because it related to audit procedures generally rather than to the specific issues raised in these show cause proceedings. The Special Master permitted claimant a period in which to submit a revised response excluding reference to this new evidence. Claimant did not submit a revised response. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had their opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. at Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had pulmonary hypertension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded there was no reasonable basis for the attesting physician's finding that claimant had pulmonary hypertension. Specifically, Dr. Abramson explained:

> The measurement of the peak velocity of the tricuspid regurgitation jet on the tape is ... obtained with inappropriate settings. The scale is too high which decreases the accuracy of the measurement. I carefully re-measured the [tricuspid regurgitation] jet three times at 2.7 m/s which calculates to an estimated pulmonary artery systolic pressure of 39 mm Hg.

After reviewing the entire show cause record, we find claimant's arguments are without merit. We disagree with

claimant that the opinions of Dr. Rubinstein, Dr. Applefeld, and Dr. Salmon provide a reasonable medical basis for Dr. Rubinstein's representation that claimant has pulmonary hypertension. As we have explained in PTO No. 2640 in connection with evaluation of a claimant's level of mitral regurgitation, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow," and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, in evaluating claimant's pulmonary hypertension, Dr. Abramson observed, and claimant did not adequately refute, that "[t]he measurement of the peak velocity of the tricuspid regurgitation jet on the tape is also obtained with inappropriate settings."[10] Dr. Abramson explained, "The scale is too high which decreases the accuracy of the measurement." Such unacceptable practices

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10. Despite an opportunity to do so, claimant did not submit a substantive response to the Technical Advisor Report. See Audit Rule 34.

cannot provide a reasonable medical basis for the resulting Green Form representation of pulmonary hypertension.

As noted, the Settlement Agreement defines pulmonary hypertension secondary to moderate or greater mitral regurgitation as peak systolic artery pressure > 40 mm Hg measured by cardiac catheterization or > 45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See Settlement Agreement § IV.B.2.c.(2)(b)iv). Dr. Abramson reviewed claimant's echocardiogram and determined that, upon "careful[] re-measure[ment]," claimant's pulmonary artery systolic pressure was 39 mm Hg. Neither claimant nor her cardiologists identified any particular error in Dr. Abramson's conclusion. Instead, claimant simply stated, "We are not going to add anything further to the Technical Advisor's Report, except that we disagree with the findings." Mere disagreement with the Technical Advisor without identifying any specific errors by her is insufficient to meet a claimant's burden of proof.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for Dr. Rubinstein's representation that the echocardiogram of April 27, 2002 demonstrates pulmonary hypertension as defined by the Settlement Agreement is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. Adopting claimant's argument would allow a claimant

to recover Matrix Benefits with a peak systolic artery pressure less than the amount required by the Settlement Agreement. This result would render meaningless this critical provision.[11]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had pulmonary hypertension. Therefore, we will affirm the Trust's denial of the claim of Ms. Whiteoak for Matrix Benefits and the related derivative claim submitted by her spouse.

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11. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement that, "there is no reasonable medical basis for the Attesting Physician's claim, even when taking into account inter-reader variability, that Susan E. Whiteoak has ... a peak systolic artery pressure >45mmHg by Doppler Echocardiography."